

ProtectTexas™

Texas Department of Health

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Nick Curry, M.D., M.P.H.
Executive Deputy Commissioner

May 3, 2004

Dear EMS Provider:

RE: Important information for all EMS Providers in Texas.

The Texas Department of Health's Bureau of Emergency Management has held a CLIA Laboratory Certificate of Waiver for all ambulances in Texas for several years. However, we have been advised not to renew the current certificate that will expire on August 31, 2004, because of legal implications for the department. Effective September 1, 2004, EMS Providers will be responsible for securing and maintaining a current CLIA Certificate of Waiver. This applies to any firm using glucometers or other devices to test blood or other patient fluids. Firms that do not use glucometers or other devices to test blood or other patient fluids are not subject to CLIA requirements.

The Clinical Laboratory Improvement Act (CLIA) of 1988 established licensing requirements for facilities (including EMS firms) performing lab tests. Even simple tests such as blood glucose testing and monitoring fall under the CLIA requirements. Fortunately, those simple tests that are commonly performed on EMS units qualify for a CLIA Certificate of Waiver. The CLIA requirements for facilities operating under the Certificate of Waiver are much lower than for other laboratories, but an application and fee are still required.

Complying with the requirements of the Certificate of Waiver is actually very easy. EMS providers are simply required to follow the equipment manufacturer's recommendations and instructions. Employees should be trained in the use of any equipment such as the device used for blood glucose testing. Additionally, a copy of the manufacturer's recommendations and instructions should be readily available if your facility is inspected by the TDH's Health Facility Compliance Division. Violations of CLIA can result in a fine of up to \$1,000 per day from the Office of Inspector General.

A downloadable application and instruction sheet for the Certificate of Waiver is available at: www.cms.hhs.gov/forms/cms116.pdf.

Fees are as follows:

- Non-Profit Organizations - \$150
 - Governmental Entities and Private Providers - \$150 per address
- (Each substation location counts as an additional address.)

Hospital-based EMS Providers may be able to work under the existing laboratory CLIA license if the director of the lab is willing to accept the responsibility.

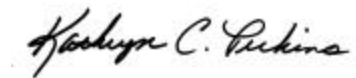
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Completed applications may be faxed to (512) 834-6653. The application is processed by the Health Facility Compliance Division. The federal government will issue a bill and the Certificate of Waiver is issued upon receipt of the fee. Additional information about CLIA is available on the web at: www.cms.hhs.gov/clia/ and www.phppo.cdc.gov/clia/regs/toc.aspx.

Please call TDH's Health Facility Compliance Division at (512) 834-6650 if you have questions concerning CLIA requirements.

Sincerely,

A handwritten signature in black ink, reading "Kathryn C. Perkins". The signature is written in a cursive style with a large, stylized 'K' and 'P'.

Kathryn Perkins, RN, MBA
Chief
Bureau of Emergency Management